Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy

Protocol summary

Summary
The goal of the present randomized clinical trial study was to asses and compare effects of Sodium thiopental versus Midazolam-Ketamine on postoperative agitation after pediatric tonsillectomy. Inclusion criteria: children aged between 5 and 15 years candidating tonsillectomy, who were group in class 1 and 2 anesthesia. Exclusion criteria : Inability to intubation, History of use barbiturates. The study was done on children, who had been referred to Valiasr hospital for tonsillectomy Totally, 50 patients between 5 and 15 years were selected based on criteria and were randomly divided into two 25 patient groups (Nesdonal and Midazolam-Ketamine group) In the first group nesdonal 5mg/kg/IV, in the second group ketamine1mg/kg and midazolam 0.01 mg/kg, were administered intravenous. level of sedation was evaluated by the Ramsay Sedation Scale postoperative

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201205066808N4**
Registration date: **2014-06-26, 1393/04/05**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2014-06-26, 1393/04/05

Registrant information
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Recruitment status
Recruitment complete
Funding source
Birjand University of Medical Sciences

Expected recruitment start date
2013-04-21, 1392/02/01
Expected recruitment end date
2013-09-21, 1392/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy

Public title
effect of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: children aged between 5 and 15 years ; class 1 and 2 anesthesia; Candid of surgery tonsillectomy
Exclusion criteria : Inability to intubation; History use of barbiturates
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Birjand, Jonoubi Khorasan, Iran
City
Birjand
Postal code
Approval date
2013-04-15, 1392/01/26
Ethics committee reference number
772

Health conditions studied

1

Description of health condition studied
tonsillectomy
ICD-10 code
J35.1
ICD-10 code description
Hypertrophy of tonsils

Primary outcomes

1

Description
Sedation score
Timepoint
postoperative
Method of measurement
Ramsay Sedation Scale

Secondary outcomes

1

Description
Pulse
Timepoint
Before, during and postoperative
Method of measurement
Pulse oximeter

2

Description
Oxygen saturation of arterial blood
Timepoint
Before, during and postoperative
Method of measurement
Pulse oximeter

Intervention groups

1

Description
nesdonal group : nesdonal 5 mg per kg
Category
Treatment - Drugs

2

Description
midazolam- ketamin group:midazolam1mg per kg and midazolam 0.01 mg per kg intrvenous
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Street address
Valiasr Hospital, Birjand University of Medical Sciences, Birjand, Jonoubi khorasan, Iran
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Gholamreza Sharifzaadeh
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Birjand University of Medical Sciences, Ghafarie

street, Birjand,Jonoubi khorasan, Iran

City

Birjand

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty